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10/647,948	08/26/2003	Harvey Jay	J07-004	4553

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R. Neil Sudol  
714 Colorado Avenue  
Bridgeport, CT 06605-1601

EXAMINER
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JOHNSON III, HENRY M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/647,948	JAY, HARVEY	
	<b>Examiner</b>	<b>Art Unit</b>	
	Henry M. Johnson, III	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-19, 22-40, 58, 59 and 67-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-19, 22-40, 58, 59 and 67-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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***Response to Arguments***

Applicant's arguments filed July 5, 2005, with respect to 35 USC § 101 and 35 USC § 112, first paragraph have been fully considered and are persuasive. The rejections of have been withdrawn.

New rejections based on new art and further examination are provided herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12-19, 22-28 and 67-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 68, 70, 72, 73 and 78 are indefinite as the intended outcome is not clear in that the term "partially prevent, reverse or inhibit" is inconsistent with the intent to prevent. The term reverse means a problem is being addressed contrary to the prevent term and to no visible undesirable condition exists on the skin surface.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 18, 19, 24 and 67-79 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent 4,882,598 to Wulf. Wulf teaches a method of controlling an individual's exposure to ultraviolet radiation for tanning said individual's skin surface in order to render it possible to expose said individual's skin surface to ultraviolet radiation without running the risk of becoming erythrodermic or erythematous or catching more serious skin diseases, such as skin cancer (Col. 2, lines 1-5). The method includes exposing a skin surface to radiation with a wavelength of 320 to 400 nanometers and additionally exposing for a short period of time to a wavelength of 280-320 nanometers (Col. 6, lines 58), the exposing disclosed as starting melanogenesis. The radiation is of a predetermined spectral composition and predetermined intensity (Col. 2, lines 20-22). The methods relate to sun tanning which is known to include multiple exposures with intervals between exposures. Wulf discloses the known fact that different skin types are more sensitive to radiation exposure than others thereby implying knowledge of the minimum erytherma dosages (MED) for skin types, as published in the well known Diffey Erythema Sensitivity Spectrum. Sun tanning is commonly associated with a beach environment and subjects armed with MED information, along with latitude and time of year, would inherently conduct a safe tanning regiment including not going the beach before 10 AM and limited exposure to MED guidelines. Such a regiment would include intervals (daily being common) and multiple exposures.

Claims 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,171,302 to Talpalriu et al. Talpalriu et al. discloses a method for irradiating skin with a light beam and since the beam does not leave any visible mark on the skin, and a marker using

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any marking fluid suitable for leaving a visible trace upon surface of the tissue (Col. 10, lines 30-33). The marking is located on the trailing end of the applicator, thus marking the tissue after irradiation. The mark is visible therefor it must contain pigment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2-9, 12-19, 24, 29-37, 40 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,882,598 to Wulf in view of U.S. Patent 6,514,243 to Eckhouse et al. Wulf is discussed above, but does not disclose a specific source of radiation. Once the methodology is established, one skilled in the art would obviously seek sources for providing the required radiation and since melanogenesis is required, skin radiation devices would be the obvious place to look. Eckhouse et al. teaches methods for electromagnetic skin treatment using pulsed light sources such as flashlamps for providing electromagnetic treatment of the skin (abstract). The flashlamp is disclosed as providing energy with a wavelength between 550 and 1300 nm (Col. 6, lines 37-38), a pulse width of less than 200 ms, and the delay between pulses is on the order of 10 to 100 ms between the pulses (Col. 6, lines 39-41). The fluence is disclosed as between 10 and 100 J/cm<sup>2</sup> (Col. 6, line 22). The parameters of the incoherent light overlap those of the application and are therefore interpreted as an effective amount of electromagnetic radiation. The method of treatment with light energy comprises the steps of providing a high power, pulsed light output from a non-laser, incoherent light source and directing the pulsed light output to a treatment area (Col 4. line 64 to Col. 5 line 1). Since the

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application may be before, during or after exposure, there are no other options, so Eckhouse must be performed at one of those optional times. The presence or absence of visible damage does not effect the production of pigment nor does it require and active step. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the source as taught by Eckhouse et al. in the method of Wulf to initiate the melanogenesis process.

Regarding claims 16 and 17, Eckhouse et al. teaches the wavelengths selected as being absorbed by melanin (Col. 21, lines 45-50).

The melanogenesis process is initiated with small radiation intensities. Those skilled in the art are well aware that pulse parameters may be used to control the fluence to the skin and also know that exposures above the MED may actually induce damage from sun burn. Lacking any data in the instant application supporting specific pulse parameters as providing any specific benefit or unexpected result, the pulse parameters are considered variables that one skilled in the art would routinely modify to optimize the process.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,882,598 to Wulf in view of U.S. Patent 6,514,243 to Eckhouse et al. as applied to claim 29 above and further in view of U.S. Patent 6,171,302 to Talpalriu et al. All are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the marking method as taught by Talpalriu et al. in the method of Wulf and Eckhouse et al. when the radiated areas cannot be identified as suggested by Talpalriu et al. as the reason for the markings on the skin.

Claims 1, and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,882,598 to Wulf in view of U.S. Patent 6,676,655 to McDaniel. Wulf is discussed above, but does not disclose a specific source of radiation. Once the methodology is

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established, one skilled in the art would obviously seek sources for providing the required radiation and since melanogenesis is required, skin radiation devices would be the obvious place to look. McDaniel teaches a method for treating various dermatological conditions using electromagnetic radiation with wavelengths from about 300 nm to about 1600 nm, and wherein said pulses have a duration of from about 0.1 femtoseconds to about 100 seconds, the interpulse delay between said pulses is from about 0.1 to about 1000 milliseconds, and the energy fluence received by said tissue is less than about  $10 \text{ J/cm}^2$  (Col. 2, lines 28-34). These parameters overlap those of the application and are therefore interpreted as an effective amount of electromagnetic radiation. The method of treatment comprises the step exposing tissue to the light of the stated parameters (Col. 2, lines 25-27). Since the application may be before, during or after exposure, there are no other options, so McDaniel must be performed at one of those optional times. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the source as taught by McDaniel in the method of Wulf to initiate the melanogenesis process as virtually any UV source could be used.

Regarding claims 25 and 26, McDaniel teaches the use of porphyrin as an excellent topical composition with superior optical properties for acting as a chromophore to enhance low-intensity light therapies (Col 22, line 33-37).

Regarding claim 27, McDaniel teaches that ultrasound may be used therapeutically to interact directly with the agent or the agent-tissue complex to produce the desired damaged target tissues (to be used alone or in combination with laser or non-laser light sources)(Col. 6, line 66 to Col. 7 line 3).

Regarding claim 28, McDaniel discloses low energy electromagnetic fields can be used alone or in combination with photomodulation (Col. 15, lines 55-60).

The melanogenesis process is initiated with small radiation intensities. Those skilled in the art are well aware that pulse parameters may be used to control the fluence to the skin and also know that exposures above the MED may actually induce damage from sun burn. Lacking any data in the instant application supporting specific pulse parameters as providing any specific benefit or unexpected result, the pulse parameters are considered variables that one skilled in the art would routinely modify to optimize the process. Likewise, the use of photosensitizers, ultrasonic and magnetic fields as taught by McDaniel have no disclosed specific benefit or unexpected results.

Claims 1, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 4,882,598 to Wulf in view of U.S. Patent 6,171,302 to Talpalriu et al. Wulf and Talpalriu et al. are discussed above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the marking method as taught by Talpalriu et al. in the method of Wulf when the radiated areas cannot be identified as suggested by Talpalriu et al. as the reason for the markings on the skin.

Claim 1, 68-69 and 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,282,842 to Changaris. Changaris discloses a method of tanning using pulsed light and teaches that tanning occurs largely through a process known as melanogenesis, a process which turns skin darker by stimulating the melanin-containing cells known as melanocytes to generate small packets of pigment (Col. 1, lines 26-30). It is well known that the increased pigment provides a degree of increased protection from further sun exposure and that the sun's radiation contains UV wavelengths. An individual, in a routine daily regiment, is exposed to sunlight multiple times, thus provoking melanogenesis. Thus the claimed method is inherent in everyday activity unless a person is in complete darkness. The action steps are applying a first radiation and applying a second radiation. Using the sun as the



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source, the melanogenesis is inherent with exposure. The criteria of an absence of a visible undesirable condition is not a action step of the method and has no effect on the outcome as melanogenesis will take place regardless of the skin condition. Thus it is obvious that a person leaving their home at 8 AM in June in the northern hemisphere and returning at 5 PM would be exposed to UV radiation and melanogenesis twice in a normal day. A person going to the beach daily, likewise would undergo the claimed method and it is inherent that sand and water reflect UV radiation, some of the exposure would be due to reflected radiation. It is also inherent that radiation will scatter in tissue unless it is focused and the incident angle is tightly controlled.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,171,302 to Talpalriu et al. in view of U.S. Patent 6,730,113 to Eckhardt et al. Talpalriu et al. is discussed above, but does not teach the use of a sensor for detecting areas radiated. Eckhouse et al. teaches sensors to detect varying skins or a difference between skin and bandage using reflectance. Such a sensor is capable of detecting reflectance of a marker dye. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the sensors to detect radiation as taught by Eckhardt et al. in the invention of Eckhouse to monitor the radiation level to insure, safe, proper levels of radiation.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent Application Publication US 2002/0145859 to Chubb et al. discloses a method for treating skin in order to reduce the risk of skin cancer (abstract) by exposing a partial body to radiation from more than 0.06 MED to not more than 0.2 MED per day. The per day teaching makes it implicit that multiple treatments are conducted at times approximating 24

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hours in separation. Other objectives disclosed are to provide a method and apparatus to have whole body radiation to reduce the cholesterol in the skin, artery plaque and other tissue; and to induce the production of vitamin D. All of these would be done without any visible skin condition as they are preventative methods. Chubb et al. further disclose significant background data on exposure and skin types indicating that the one skilled in the art would be knowledgeable of the interactions of the many variables of wavelength, dosage and skin types.


U.S. Patent 6,828,576 to Spivak teaches a light emitting diode apparatus and method for irradiating a subject with ultraviolet radiation, comprising a plurality of light emitting diodes configured to emit ultraviolet radiation and arranged in a matrix, and a power modulation control (interpreted as pulsed) unit in communication with the diodes. The power modulation control unit is configured to energize and cause the diodes to emit light and thereby irradiate the subject with ultraviolet radiation sufficient to cause material physical change in the subject. In one embodiment of the invention, the material physical change is skin tanning. The amount, intensity, duration and type of UVR projected by the plurality of UV LED's may be varied by the power modulation control unit responsive to information input into the power modulation control unit (abstract). Spivak. Discloses that tanning occurs when the skin produces additional pigment coloring) to protect itself against burning from ultraviolet radiation (UVR), thus such exposure is able to provide protection to prevent or inhibit damage from additional exposure. Spivak teaches the effect of skin types on tolerance of radiation. With tanning and vitamin D production as intended results, no pre-existing conditions would be visible.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Henry M. Johnson, III  
Primary Examiner  
Art Unit 3739